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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,998	10/16/2003	Patrick J. Sweeney	029815-0103	7428

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EXAMINER

BARRETT, THOMAS C

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/686,998	Applicant(s) SWEENEY, PATRICK J.	
	Examiner Thomas C. Barrett	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-15,17,18,21-25,27-30,32-34,36-41,43,61-66 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) 10,12,18,22,28,37,43,66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-9,11,13-15,17,21,23-25,27,29,30,32-34,36-41,62-65,68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 5-15, 17-18, 21-25, 27-30, 32-34, 36-41, 43, 61-66 and 68-70 have been considered but are moot in view of the new ground(s) of rejection.

In regards to newly amended claims 11-15, 21-25 and 27-30, the recitation "and an artificial spinal disc" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant to be claimed by the limitation "wherein the artificial spinal disc comprises a core disposed between two plates and wherein one of the two plates is removed prior to being coupled with the

structure.” Is it intended to be, e.g., a product by process limitation, or is the plate put back on once the disc is coupled to the structure, etc?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Downey (5,147,404) as cited in Applicant’s IDS. Downey discloses a spinal implant system, comprising: a vertebral prosthesis and an endplate, and an artificial spinal disc threaded into a recess on the endplate (Fig. 2).

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Buttermann (5,827,328). A spinal implant system (e.g. FIG. 7), comprising: a vertebral prosthesis (78) having a support and an endplate, and an artificial spinal disc (82) coupled to the endplate that comprises a core between two plates.

Please note the 112 rejection supra in regards to the product by process limitation, which can be interpreted in several ways.

Claims 11, 13-15, 17, 21, 23-25, 27, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbe et al. (5,702,453) as cited in Applicant’s IDS. Rabbe et al. discloses a spinal implant system, comprising: a vertebral prosthesis

having a support and an endplate, wherein the support is adjustable to change the height of the vertebral prosthesis (Fig. 3); screw retainer (e.g. 46) and a pedicle screw (e.g. 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 11, 13-15, 17, 21, 23-25, 27, 29-30, 32-34, 36, 38-41, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al. (5,702,453) in view of Downey (5,147,404) as cited in Applicant's IDS. Rabbe et al. discloses a spinal implant system as above. However, Rabbe et al. does not disclose the implant coupled to an artificial disc. Downey teaches the use of an artificial disc coupled to a vertebral prosthesis (e.g. col. 3, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an artificial disc of Downey, to the vertebral prosthesis of Rabbe, so that "relatively little, if any flexibility is lost" as found in Downey (col. 2, lines 48-57).

Claims 61-65 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strnad et al. (6,296,665) in view of Downey (5,147,404) as cited in Applicant's IDS. Strnad et al. discloses a spinal implant system (Figs. 8a-9), comprising: a vertebral prosthesis having a support and an endplate, wherein the support is

adjustable by sliding and uses a locking ring (110), a pedicle screw and retainer (202). However, Strnad et al. does not disclose the implant coupled to an artificial disc. Downey teaches the use of an artificial disc coupled to a vertebral prosthesis (e.g. col. 3, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an artificial disc of Downey, to the vertebral prosthesis of Strnad et al., so that "relatively little, if any flexibility is lost" as found in Downey (col. 2, lines 48-57).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett
Examiner
Art Unit: 3738